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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,074	09/28/2000	Philip Henry Coelho	30111-pa	4198

7590

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EXAMINER

OLSEN, KAJ K

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 11/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/672,074

Applicant(s)

COELHO ET AL.

Examiner

Kaj Olsen

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 11-13, 19-23, 28-32 and 45-62 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 11-13, 28-32 and 45-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-23 and 56-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of 8-13-2001 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that it is improper to restrict process and apparatus claims involving the same inventive concept. However, restrictions under 35 U.S.C. 121 do not require the claims to be drawn to different inventive concepts per se when the inventive concept is claimed in such a manner that it qualifies as being distinct under 35 U.S.C. 121 (see MPEP 806). Just because the claimed inventions might be coextensive does not mean the claimed inventions are not distinct. Applicant also urges that the examination of all the claimed subject matter would not present a serious burden on the U.S. Patent and Trademark Office. This is not found persuasive because of the unsupported assumption that an examination of apparatus claims are coextensive with the examination of process claims. Even though there may be overlap between the subject matter, the searches would certainly not be identical as evidenced by the difference in classification.

The requirement is still deemed proper and is therefore made FINAL.

### ***Drawings***

Figures 8 and 13 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g).

Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-23 and 56-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 19 and 60, the term “the recess formed in the sheet” lacks antecedent basis. The recess was associated with the mold but not the sheet itself.

The preamble of claims 19 and 60 states the invention is drawn to a method of forming a bag, but claims 58, 59, and 62 appear to be drawn to a method of using the bag making it unclear what class of statutory invention the applicant is claiming (a process of making or a process of use?).

Claim 23 specifies the formation of a plurality of portals, but the applicant has only specified a singular recess for the first and second molds. A single recess would not appear to be able to form a plurality of portals making it unclear if the applicant is claiming the step of forming a plurality of portals or merely the formation of a single portal.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Medwed (USP 4,397,804).

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Medwed discloses a forming a container (i.e. bag) which comprises forming a first mold having a recess including a planar surface, a radiused periphery circumscribing said planar surface, and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface (fig. 2 as an example). A sheet is placed over said mold and is caused to conform to the mold and retains having the configuration of the mold (fig. 1 and 4). The conformed sheet is removed from the mold and the first sheet is closed with another sheet parallel to the planar surface (fig. 1 again).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 19-23, 56, 57, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sneider (USP 4,591,357) in view of Heck (USP 4,428,743) with or without evidence by Nathoo (USP 4,943,222) or Medwed (USP 4,397,804).

Sneider discloses a container having a planar wall, a radiused periphery and a peripheral ledge which retains its shape (fig. 1 and 2). However, Sneider does not explicitly identify how the container is constructed. Heck teaches in an alternate medical container that medical containers can be constructed by a number of conventional ways including blow molding as well as vacuum molding individual halves (col. 2, lines 29-39). Nathoo evidences that vacuum molded halves are less susceptible to tearing (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the formation of the container of Sneider because the prior art recognized that vacuum molding is a conventional means for constructing medical containers. In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the container of Sneider as evidenced by Nathoo because vacuum formed devices are less susceptible to tearing. Both Nathoo and Medwed evidence that vacuum molded halves contain peripheral flashings. Sneider discloses a plurality of portals (fig. 1 and 2) and the teaching of Sneider in view of Heck would result in the use of two molds each having the claimed shape. With respect to claim 60 (those limitations not covered above) a container having the set forth shape would inherently be resistant to forces engendered by medical fluid undergoing a phase change. The container of Sneider is disclosed as utilized for medicines requiring dilution and medicines can include thermolabile or biological substances. Portal 16 would be closed during mixing.

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Claims 19-23, 56, 57, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk et al (USP 5,108,387) in view of Heck (USP 4,428,743) with or without evidence by Nathoo (USP 4,943,222) or Medwed (USP 4,397,804).

Falk discloses a container having a planar wall, a radiused periphery and a peripheral ledge which retains its shape (fig. 1a). However, <sup>Falk</sup>Sneider does not explicitly identify how the container is constructed. Heck teaches in an alternate medical container that medical containers can be constructed by a number of conventional ways including blow molding as well as vacuum molding individual halves (col. 2, lines 29-39). Nathoo evidences that vacuum molded halves are less susceptible to tearing (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the formation of the container of Falk because the prior art recognized that vacuum molding is a conventional means for constructing medical containers. In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the container of Sneider as evidenced by Nathoo because vacuum formed devices are less susceptible to tearing. Both Nathoo and Medwed evidence that vacuum molded halves contain peripheral flashings. Falk discloses a plurality of portals (5, 6) of which 5 is sealed after filling (col. 4, lines 10-28) and the teaching of Falk in view of Heck would result in the use of two molds each having the claimed shape. With respect to claim 60 (those limitations not covered above) a container having the set forth shape would inherently be resistant to forces engendered by medical fluid undergoing a phase change. Falk teaches utilizing the container for dialysis concentrates which can include thermolabile or biological substances such as enzymes or antibodies.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medwed.

Medwed set forth all the limitations of the claims, but didn't identify having the containers contain either thermolabile or cellular biological substances. Medwed is disclosed for use with food (col. 1, lines 9 and 10) and a number of food products (e.g. meats, vegetables, etc) would qualify as the materials of claims 20 and 21. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the container of Medwed for foods containing thermolabile or cellular biological substances because the container of Medwed has been identified as a convenient container for packaging and storing of foods.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 8:00 AM-5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for this Group is (703) 305-7719.



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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

Kaj K. Olsen, Ph.D.

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a long horizontal flourish extending to the right.

Patent Examiner

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A handwritten signature in black ink, appearing to read 'Robert J. Warden, Sr.', with a stylized 'R' and 'W'.

ROBERT J. WARDEN, SR.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700